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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/027,671	02/23/1998	ALAN K. SMITH	4292-0048-55	3507

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/05/2001

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

027,671

Applicant(s)

SMITH et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9/27/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 6-12, 38-47 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 6-12, 38-47 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The request filed on 9/27/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/027,671 is acceptable and a CPA has been established. An action on the CPA follows.

The disclosure is objected to because of the following informalities: at page 19, line 20 applicant is requested to update the status of the referenced application and delete the docket no.

Appropriate correction is required.

Claim 42 is objected to because of the following informalities: In claim 42, -- hepatocytes-- has been misspelled. Appropriate correction is required.

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Recitation of "periodically or continuously" encompasses all possible embodiments of the "replacement" recited in claim 38. Claim 9 thus fails to narrow the scope of base claim 38.

Applicant is advised that should claim 12 be found allowable, claim 46 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Claims 6-12 and 38-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In base claim 38, line 3 "the liquid culture medium" lacks antecedent basis.

In claim 38, lines 1 and 4 "enhanced" is unclear because the term is not defined in relation to any baseline function which would be considered as not "enhanced".

Furthermore claim 38 fails to adequately define the invention because it requires⁵ nothing more than the replacement of the culture medium. Replacement of such is art conventional for maintaining any expandable cell culture, whether in culture dishes/flasks or in a hollow fiber device. The mere recitation that such replacement results in "enhanced biological function" fails to define the invention over what is art conventional, because as noted supra "enhanced" is not defined according to any baseline standard, over which the biological function is "enhanced". Applicant has thus utterly failed to define the metes and bounds of the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Claims 8-12, 38-40, 42-43 and 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Emerson et al. (5,437,994).

Emerson et al. teach the culturing of human hematopoietic progenitor cells, at various rates of changing the fluid culture media. Emerson et al. show that 3.5 changes of medium per

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week lead to the most prolific production of granulocyte-macrophage progenitors. See col. 7, lines 43-48; col. 18, line 62-col. 19, line 42. Enhanced proliferation of such cells in within the scope of what applicant considers to be an “enhanced biological function” (e.g. instant claims 12, 39 and 46).

In like manner, Emerson et al. show that rapid medium exchange increases the secretion of GM-CSF and IL-6 from cultures stromal cells. See col. 7, line 60- col. 8, line 12. Enhanced secretion is within the scope of an “enhanced biological function” (instant claims 39-40).

Regarding claim 8, note claim 23 of Emerson et al. And note col. 5, line 66 - col. 6 line 5, wherein an exchange rate of 1 ml per ml of culture per 24 hours translates to the instantly recited value of “100% daily”.

Regarding instant claims 9 and 47, note col. 6, lines 9-22 and claim 24.

With respect to instant claim 10, note experimental condition disclosed at cols. 17-24 show culturing for several weeks.

Regarding claim 11, note col. 6, lines 23-48; col. 22, line 32 - col. 24, line 2.

Claims 6, 9-12, 38-39, 41-42 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Freedman et al. (Jour. Immunol.. Meth, 167,145, 1994).

Freedman et al. teach a four step method of growing tumor-infiltrating lymphocytes (TILs) from cancer Patients. The last of the four steps involves expansion of the cells in a hollow fiber or artificial capillary system (ACCS). Fresh media were added to the ACCS device, according to measured glucose consumption (page 148, column 2, first full paragraph). This

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fourth step is considered consistent with what is claimed, since culturing of TILs in the ACCS permitted a greater expansion of cell numbers in accord with instant claims 12, 39 and 46.

Further in some cases the step of culturing in the ACCS resulted in an increased number of TILS that exhibited preferential killing of autologous tumor cells (page 157, paragraph spanning cols. 1-2), in accord with instant claims 39 and 41.

Regarding dependent claims 9-10 note page 148, column 2, first full paragraph).

Regarding claim 11, the added RIL-2 (page 148, third full paragraph) is considered to be a "growth factor", since applicant has discussed IL-2 (specification page 16) under the heading of "Growth Factors".

Regarding claim 44, the T-lymphocytes cultured by Freedman et al. inherently constitute "non-myeloid" cells because lymphoid cells are properly considered to be non-myeloid cells.

Note, distinction of the myeloid and lymphoid cells in the scheme given by Clark.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on M-F from 8:15 a.m. to 4:45 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

Nov. 26, 2001

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644